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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1729]

Revocation of Emergency Use of a Drug During the COVID-19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Fresenius Kabi USA, LLC (Fresenius Kabi), for Fresenius Propoven 2% Emulsion. FDA revoked the Authorization on May 10, 2022, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of May 10, 2022.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization

Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 8, 2020, FDA issued an Authorization (EUA 050) to Fresenius Kabi for Fresenius Propoven 2% Emulsion, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the *Federal Register* on September 11, 2020 (85 FR 56231), as required by section 564(h)(1) of the FD&C Act. The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on April 8, 2022, Fresenius Kabi requested revocation of, and on May 10, 2022, FDA revoked, the Authorization for the Fresenius Propoven 2% Emulsion. Because Fresenius Kabi notified FDA that it does not intend to offer the Fresenius Propoven 2% Emulsion in the United States anymore and requested FDA revoke the EUA for the Fresenius Propoven 2% Emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at https://www.regulations.gov/.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for Fresenius Kabi's

Fresenius Propoven 2% Emulsion. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

May 10, 2022

Nicole Chutipisalkul
Sr. Regulatory Affairs Specialist
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Revocation of EUA 050 – Propoven 2% Emulsion

Dear Ms. Chutipisalkul:

This letter is in response to the request from Fresenius Kabi USA, LLC ("Fresenius Kabi"), received on April 8, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Fresenius Propoven 2% Emulsion issued on May 8, 2020. Fresenius Kabi has informed the FDA that the inventory of the Fresenius Propoven 2% emulsion within the United States has been depleted and that Fresenius Kabi does not intend to offer this product in the United States anymore. FDA understands Fresenius Kabi has notified healthcare facilities and providers that have received the Fresenius Propoven 2% Emulsion under the EUA to also stop using this product.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Fresenius Kabi has notified FDA that it does not intend to offer the Fresenius Propoven 2% Emulsion in the United States anymore and requested FDA revoke the EUA for the Fresenius Propoven 2% Emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 050 for the Fresenius Propoven 2% Emulsion, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Fresenius Propoven 2% Emulsion is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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